REMARKS/ARGUMENTS

Reconsideration of this application and entry of the foregoing amendments are respectfully requested.

Claims 1 and 12 have been revised so as to be drawn to a method of "treating or inhibiting progression of cerebral vasospasm". The claims as presented are fully supported by an enabling disclosure, including the Examples which indicate that active agents of the invention can ameliorate progression of cerebral vasospasm associated with SAH. That the claims have been revised should not be taken as an indication that Applicants agree with any view expressed by the Examiner. Rather the revisions are made merely to advance prosecution and Applicants reserve the right to pursue any deleted subject matter in a continuation application.

Claim 1 stands rejected under 35 USC 112, first paragraph, as allegedly being non-enabled. The rejection is traversed.

The Examiner contends that the subject specification "does not reasonably provide enablement for any compounds for inhibiting vascular cell proliferation". The Examiner further contends that undue experimentation would be required to practice the invention as claimed. Applicants respectfully disagree.

To satisfy the enablement requirement of 35 USC 112, first paragraph, a patent application must adequately disclose the claimed invention so as to enable a person skilled in the art to practice the invention at the time the application was filed without undue experimentation. Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371-72,

52 USPQ2d 1129, 1136 (Fed. Cir. 1999). It should be noted that "nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). As set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993):

> When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

In rejecting the claims as non-enabled, the Examiner contends that Applicants' claims are "functional at the point of novelty". There is absolutely no basis for this assertion.

The present claims are drawn to a method of treating or inhibiting progression of cerebral vasospasm. In the case of claim 1, the method comprises administration of an agent that inhibits vascular cell proliferation. In the case of claim 12, the method comprises administration of an agent that inhibits extracellular matrix synthesis or secretion or weakens or degrades extracellular matrix. The novelty of the claimed methods results not from the specific nature of the agent used, but rather from the fact that Applicants were the first to appreciate and disclose that narrowing of cerebral arteries that is characteristic of cerebral vasospasm is in fact due to proliferation of cells

in the vascular wall and/or accumulation of extracellular matrix under the influence of growth factors.

As taught by the subject specification, innumerable known agents can be used in Applicants' novel methods. At pages 7-10 of the application, a large number and wide variety of suitable agents are described. (Applicants also provide, at pages 10-12 of the application, methods of identifying yet further agents that would be suitable for use in the invention.) Conspicuous by its absence is any comment from the Examiner as to why the extensive description of suitable agents provided is inadequate and why any undue burden would be required of one skilled in the art to merely select an agent from those taught.

The relevance of the Examiner's comments on page 6 of the Action relating to drug-drug interactions is not seen. Indeed, the Examiner provides no explanation as to why such effects are any more relevant to the claimed methods than they are to other medical therapy. The issues to which the Examiner refers are one well known and commonly addressed by those skilled in the relevant art.

The Examiner's assertions to the contrary, one wishing to practice the claimed invention would not be required to bear any undue burden. No "exhausted" search for compounds would be required. Rather, one would merely have to select a compound from the many taught in the subject specification and administer it as taught. The Examiner provides nothing by way of explanation as to why anything further would be required. Reconsideration is requested.

Claims 1, 10 and 11 stand rejected under 35 USC 112, first paragraph, as allegedly being non-enabled. This rejection appears to be based on the Examiner's objection to the use of the term "preventing". While in no way agreeing with the Examiner's position, the claims have been amended to make reference to "inhibiting progression of" rather than "preventing". Reconsideration is therefore requested.

On page 10 of the Action, the Examiner rejects claims 1, 10 and 11 under 35 USC 102(b) as allegedly being anticipated by Black. The rejection is traversed for the reasons that follow.

Black et al relates to "a method for selectively opening abnormal brain tissue capillaries ... to allow selective passage of ... neuropharmaceutical agents into abnormal tissue." Subarachnoid hemorrhage (SAH) is indicated as being an example of a specific type of abnormal brain tissue. (See paragraph bridging columns 3 and 4 of Black.)

Cerebral vasospasm is a complication of SAH that generally has peak clinical manifestations at 7-10 days following SAH. The syndrome is characterized by diffuse narrowing of cerebral arteries in the general region of the SAH. The present invention relates to methods of treating, or inhibiting progression of, this complication/syndrome which, left unaddressed, can become so severe that blood flow to previously undamaged brain is compromised, resulting in risk of subsequent stroke.

While Black et al makes reference to SAH as a specific type of abnormal brain tissue to which his method is applicable, the citation would in no way have suggested the presently claimed approach to treating, or inhibiting progression of, the cerebral

vasospasm complication of SAH that Applicants have realized is due to the proliferation of cells in the vascular wall and/or accumulation of extracellular matrix. Accordingly, Black et al does not teach Applicants' claimed invention, nor would it have rendered that invention obvious. Reconsideration is requested.

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

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